

### Reasons for Allowance

Applicants' Supplemental Amendment filed March 31, 2008 is acknowledged. A Supplemental Reissue Declaration under 37 C.F.R. § § 1.172 and 1.175 filed March 31, 2008 is further acknowledged. Claims 1-6, 9, 12-15, 17, 18, 22, 23 and 26-30 are canceled. Claims 7, 8, 10, 11, 16, 19-21, 24 and 25 remain under consideration.

A clean copy of those claims not issued in U.S. Patent 5,902,821, with underlining to show added material relative to the issued claims, is noted.

Subsequent to the cancellation of claim 9, the rejection of record under 35 U.S.C. 102(a) is moot.

Subsequent to the cancellation of claims 1-6, 14, 15, 17, 18, 22, 23 and 26-30, the rejection of record under 35 U.S.C. 112, first paragraph, directed to new matter, is moot.

Clear support for the amendment to independent claims 7, 10 and 20, drawn to "a risk of " mortality, is found in the original disclosure, *inter alia*, in column 8, lines 14-15. Treatment with carvedilol resulted in a 67% reduction in the risk of all-cause mortality.

Treatment of congestive heart failure with carvedilol was known in the prior art. However, the triple-tiered dosing regimen, as set forth in the instant methods, to decrease the risk of mortality is not taught or suggested by the prior art. Accordingly, claims 7, 8, 10, 11, 16, 19-21, 24 and 25 are allowed in view of the contemporary knowledge of the art.

### EXAMINER'S AMENDMENT

An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to Applicants, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mark Feldstein on April 23, 2008.

In the Abstract before "mortality," -- risk of -- is inserted.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The examiner can normally be reached on 10:30 AM-7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached on 591-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1614

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

April 23, 2008

/Phyllis G. Spivack/  
Primary Examiner, Art Unit 1614